

148



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,607	07/31/2001	Jeremy Minshull	02-106410US	3959

30560 7590 06/09/2005

MAXYGEN, INC.
INTELLECTUAL PROPERTY DEPARTMENT
515 GALVESTON DRIVE
RED WOOD CITY, CA 94063

EXAMINER

TRAN, MY CHAU T

ART UNIT PAPER NUMBER

1639

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	09/920,607	Applicant(s)	MINSHULL ET AL.
Examiner	MY-CHAU T. TRAN	Art Unit	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 April 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-144 is/are pending in the application.
- 4a) Of the above claim(s) 1-68, 73-130, 132, 133 and 136-139 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 69-72, 131, 134, 135 and 140-144 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 31 July 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date See Office Action.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Application and Claims Status

1. Applicant's response filed 04/07/2005 is acknowledged and entered.
2. Claims 69, and 71 were amended and Claims 131-144 were added by the amendment filed on 10/01/2004.
3. Claims 1-144 are pending.

Election/Restrictions

4. Claims 1-66, and 73-130 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *nonelected inventions*, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/22/2002.
5. Claims 67-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *a nonelected invention*, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/30/2003.
6. Applicant has elected the following species for the elected invention (Claims 69-72, and 131-144) in the reply filed on 04/07/2005:
 - a. A single specific species of enzyme. Applicant has elected enzymes having specificity for metabolite, i.e. claim 131.

Priority

7. It is noted that this instant application claims benefit to two provisional applications under 35 U.S.C 119(e). They are 60/222,056 filed 07/31/2000, and 60/244,764 filed 10/31/2000. Thus, the instant application is granted the benefit of priority for both provisional applications, i.e. 60/222,056 filed 07/31/2000, and 60/244,764 filed 10/31/2000.

Information Disclosure Statement

8. The information disclosure statements (IDS) filed on 12/06/2001, and 11/05/2003 have been reviewed, and its references have been considered as noted on PTO-1449 forms.

9. Claims 69-72, 131, 134, 135, and 140-144 are treated on the merit in this Office Action.

New Rejection(s) – Necessitated by Amendment

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. *The presently claimed invention recites a biosensor, i.e. an apparatus. The apparatus comprises (a) a solid support; (b) a plurality of enzymes immobilized on the solid support; (c) a detection system; and (d) a data storage system.*

Art Unit: 1639

The plurality of enzymes comprises enzymes having different small molecule substrate specificities. The detection system is capable of detecting a reaction product from a reaction catalyzed by each of the enzymes in the plurality of enzymes, either directly or indirectly. The data corresponding to detected reaction product from reactions catalyzed by each of the enzymes in the plurality of enzymes is recorded in the data storage system. These recited limitations are functional limitation and/or functional property of the claimed enzymes, detection system, and data storage system, respectively.

12. Claims 69-72, 131, and 140-144 are rejected under 35 U.S.C. 102(b) as being anticipated by Hale et al. (*JACS*, **1989**, 111(9), pgs. 3482-3484).

Hale et al. disclose a biosensor (see e.g. pg. 3482, right col., lines 1-5, and lines 23-25; pg. 3483, fig. 2, description; pg. 3483, right col., lines 25-30). The biosensor comprises electrodes (refers to instant claimed detection system, and claims 70 and 141), and a cyclic voltammeter (refers to instant claimed data storage system, and claim 72) (see e.g. pg. 3482, right col., lines 1-5, and lines 23-25; pg. 3483, fig. 2, description). The electrodes comprise a glass electrode housing (refers to instant claimed solid support), carbon paste (refers to instant claimed matrix, and claim 140), ferrocene-modified polymer (refers to instant claims 143-144), and 10 mg of glucose oxidases (refers to instant claimed plurality of enzymes, and claim 131) (see e.g. pg. 3482, right col., lines 1-5, and lines 23-25; pg. 3483, fig. 2, description). The glucose oxidases are mix with the carbon paste and ferrocene-modified polymer (refers to instant claimed "*a plurality of enzymes immobilized on the solid support*", and claims 71, and 142) (see e.g. fig. 2, description). Thus, the biosensor of Hale et al. anticipates the presently claimed apparatus.

13. Claims 69-72, 131, and 140-143 are rejected under 35 U.S.C. 102(b) as being anticipated by Hu et al. (*Analytical Sciences*, **June 1999**, 15(6), pgs. 585-588).

Art Unit: 1639

Hu et al. disclose a glucose biosensor (see e.g. pg. 585, left col., line 33 thru right col., line 4; pg. 586, left col., lines 10-21; pg. 587, left col., lines 10-32). The biosensor comprises the electrode (refers to instant claimed detection system, and claims 70 and 141), and a cyclic voltammeter that comprises a potentialstat and a recorder (refers to instant claimed data storage system, and claim 72) (see e.g. pg. 585, left col., line 33 thru right col., line 4; pg. 586, left col., lines 22-46; fig. 1). The electrode comprises a Plexiglass cylinder (refers to instant claimed solid support), a Nafion-methyl viologen modified carbon paste electrode (refers to instant claimed matrix, and claims 140, and 143), polyaniline film, and 2.5 mg/ml of glucose oxidases (refers to instant claimed plurality of enzymes, and claim 131) (pg. 585, left col., line 33 thru right col., line 4; pg. 585, right col., line 38 thru pg. 586, left col., line 21). The glucose oxidases are immobilized on the electrode (refers to instant claimed "*a plurality of enzymes immobilized on the solid support*", and claims 71, and 142) (see e.g. pg. 585, left col., line 33 thru right col., line 4; pg. 586, lines 10-21). Thus, the biosensor of Hu et al. anticipates the presently claimed apparatus.

14. Claims 69-72, 131, 134, and 140 are rejected under 35 U.S.C. 102(b) as being anticipated by Barrett et al. (US Patent 5,482,867).

Barrett et al. disclose an array of spatially addressable array of anti-ligands immobilized on a solid substrate (refers to instant claimed "*a plurality of enzymes immobilized on the solid support*", and claims 71 and 134) (see e.g. Abstract; col. 2, lines 36-49; col. 5, lines 4-20). The array comprises a solid substrate (refers to instant claimed solid support) (see e.g. col. 3, line 62 thru col. 4, line 2; col. 7, lines 46-65), a surface comprises polymer such as aryl acetylenes

Art Unit: 1639

(refers to instant claimed non-biological polymeric matrix, and claim 140) (see e.g. col. 4, lines 3-7; col. 7, line 66 thru col. 8, line 21), a plurality of anti-ligands that include enzymes and lectins (refers to instant claimed plurality of enzymes, and claim 131) (see e.g. col. 4, lines 34-60; col. 19, line 60 thru col. 20, line 2). The array is use for screening and/or assays wherein the labeled ligands binds with the immobilized anti-ligand, and labels are detected with a detection system such as charge-coupled device (CCD), fluorescence microscopy (refers to instant claimed detection system/data storage system, and claims 70) (see e.g. col. 21, lines 7-64). Thus, the array of Barrett et al. anticipates the presently claimed apparatus.

15. Claims 69-72, 131, 134, 135, and 140-142 are rejected under 35 U.S.C. 102(e) as being anticipated by Keen (US Patent 6,060,327).

Keen discloses a sensor (see e.g. Abstract; col. 7, line 44 thru col. 8, line 28; col. 9, lines 3-24; col. 11, lines 45-60). The sensor comprises a plurality of conductive polymer strands (refers to instant claimed non-biological polymeric matrix), a plurality of recognition headgroups having an affinity for the analyte component and attached to the first ends of the conductive polymer strands (refers to instant claimed "*a plurality of enzymes immobilized on the solid support*", and claims 71, 134, and 142), and an electrode substrate attached to the conductive polymer strands at the second ends (refers to instant claimed solid support) (see e.g. col. 7, line 44 thru col. 8, line 28; col. 9, lines 3-24; col. 12, line 38 thru col. 13, line 53; figs. 2 and 3). The sensor is also divided into a plurality of regions wherein each comprises a different headgroups that detect different analytes (refers to instant claims 134, and 135) (see e.g. col. 10, lines 13-28; col. 14, line 57 thru col. 15, line 22). The types of polymer strands include polymers such as

Art Unit: 1639

aromatic metal-doped polymers (refers to instant claimed non-biological polymeric matrix, and claim 140) (see e.g. col. 25, lines 3-65). The types of headgroups include enzymes such as lipases and oxidoreductases (refers to instant claimed plurality of enzymes, and claim 131). The sensor is connected to a digital multimeter that measures the circuit output (refers to instant claimed detection system, and claims 70 and 141) (see e.g. col. 39, lines 7-45; figs 5 and 6) or connected to instruments such as a pen-based digital meter or lab-based instruments (refers to instant claimed detection system/data storage system, and claims 72) (see e.g. col. 39, line 46 thru col. 40, line 3). Thus, the sensor of Keen anticipates the presently claimed apparatus.

Withdrawn Objection(s) and /or Rejection(s)

16. The rejections of claims 69-72 under 35 USC 112, second paragraph, as being indefinite has been withdrawn in light of applicant's amendments of claim 69.

17. The rejection of claims 69-70, and 72 under 35 USC 102(b) as being anticipated by Pirrung et al. (US Patent 5,143,854) has been withdrawn in light of applicant's amendments of claim 69.

18. The rejection of claims 69-72 under 35 USC 102(b) as being anticipated by Heller et al. (US Patent 5,605,662) has been withdrawn in light of applicant's amendments of claim 69.

Art Unit: 1639

19. The rejection of claims 69-72 under 35 USC 102(e) as being anticipated by Wagner et al. (US Patent 6,329,209 B1; *filing date 7/14/1999*) has been withdrawn in light of applicant's amendments of claim 69.

Response to Arguments

20. Applicant's arguments with respect to claims 69-72 have been considered but are moot in view of the new grounds of rejections.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810.

Art Unit: 1639

The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
June 4, 2005


PADMASHRI PONNALURI
PRIMARY EXAMINER